October 8, 2021

Vascular Solutions, Inc.
Deborah Neymark
VP, RA, Clinical Research & Quality Systems
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K042937
Trade/Device Name: Pronto Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Deborah Neymark:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 31, 2005. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.08 10:30:17 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2005

Ms. Deborah Neymark
Vice President, Regulatory Affairs
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Re: K042937
Trade/Device Name: Pronto™ Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: December 23, 2004
Received: January 4, 2005

Dear Ms. Neymark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042937

Device Name: Vascular Solutions Pronto™ Extraction Catheter

Indications For Use:

The Vascular Solutions Pronto Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels of the arterial systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Lechner

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f Cardiovascular Devices

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K042937

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 3 1 2005

Common/Usual Name:	Embolectomy Catheter
Product Trade Name:	Pronto Extraction Catheter
Classification Name:	Class II 21 CFR 870.5150 Product Code, DXE
Manufacturer:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, Minnesota 55369
Establishment Registration:	2134812
Contact:	Deborah Neymark Vice President, Regulatory Affairs
Performance Standards:	No performance standards have been developed under section 514 for this device.

Device Description:
The Pronto extraction catheter is a dual lumen catheter with related accessories. The extraction lumen allows for the aspiration and removal of emboli/thrombi using the included syringe, extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of emboli/thrombi through the extraction lumen. Incorporated within the catheter distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization. Two visible markers are located on the shaft of the catheter to provide guidance to the user concerning the relative position of the Pronto and the associated guide catheter. The catheter is a monorail design with a distal flexible region and a proximal stiff region. The catheter has an approximate outer diameter of 0.065 inches, allowing delivery through standard 6Fr. guide catheters. The smaller wire lumen of the catheter is able to accommodate guide wires that are $\leq$0.014" in diameter. The catheter will be available in working lengths of 40 to 145 cm, in increments of 15 cm. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of the catheter to the included extension line, stopcock, and syringe. A 74 micron filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of thrombus.

Intended Use:
The Pronto Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Summary of Non-Clinical Testing:
Non-clinical testing of this product modification included assessments of the durability of the marker bands and the mid-shaft bond.

Summary of Clinical Testing:
No clinical evaluations of this product for this use have been conducted.

Predicate Devices:
Currently marketed Pronto Extraction Catheter (K032763)

Conclusions:
The modified Pronto is substantially equivalent to the currently marketed Vascular Solutions Inc. Pronto Extraction Catheter.